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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/297,090	07/09/99	GORANSSON L	REF/970230/L

EXAMINER	
WANG, S	
ART UNIT	**PAPER NUMBER**
1617	15

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DATE MAILED: 08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

Office Action Summary	Application N .	Applicant(s)	
	09/297,090	GORANSSON ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

1. The request filed on June 12, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/297090 is acceptable and a CPA has been established. An action on the CPA follows.

Specification Objection

2. The attempt to incorporate subject matter into this application by reference to SE 9000028-2 is improper because essential material in the specification can be incorporated only by reference to an issued US Patent. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Rejection 35 U.S.C. 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 26-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 26 recites "antisecretory proteins" (ASP). The claims or the specification does not clearly define the term "antisecretory proteins", and is confusing with respect to the definition of "antisecretory protein", particularly when referred to SE 90000028-2 (equal to US 5,296,243). The antisecretory proteins herein are termed "feed induced lectins" (FIL). The claims are indefinite as to the ASP encompassed thereby.

Claim Rejections 35 U.S.C. 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 26-28, 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnston (U.S. Patent 5,565,225).

Johnstone teaches a method for preventing diarrhea of young animal by feeding the animal a food product prepared from malted grain, particularly, malted barley. See, the abstract. A method preventing diarrhea is seen to the skill the artisan to possess the process of regulating the flux of fluid and electrolyte in the intestine. The method herein would be considered inherently possess the limitation "1 ml of blood of said animal will contain at least 0.5 units of antisecretory proteins." Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to treating or preventing a malady or disease with old and well known compounds or

compositions. It is now well settled law that administering compounds inherently possessing a therapeutic utility anticipates claims directed to such therapeutic use. Arguments that such therapeutic use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the instant application, Applicants' failure to distance the proffered claims from the anticipated therapeutic utility, renders such claims anticipated by the prior inherent use.

Claim Rejections 35 U.S.C. – 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 26-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston (US 5,565,225) in view of Lange et al. (U.S. 5,296,243) and in further view of Robbins et al. (CAPlus abstract, AN 1972:111657) and Aspinal et al. (Caplus abstract, AN 1956:30292).

Johnston teaches a method for preventing diarrhea of young animal by feeding the animal a food product prepared from malted grain, particularly, malted barley. A similar method

may also applied to human. See, particularly, the abstract. A method preventing diarrhea is seen to the skill the artisan to possess the process of regulating the flux of fluid and electrolyte in the intestine.

Johnstone does not teach expressly to increase the ASP in the animal blood to 0.5 unit/ml.

However, Lange teaches a method for regulating flux fluid and electrolyte in the intestine of an animal and reducing diarrhea in animal comprising administering to the animal a food enriched in amino acid and sugars and or amino acids. The method leads to an APS concentration of greater than 0.5 unit/ml in the animal blood. See, the abstract, table VI and table VIII in column 5 and 6, and the claims. Robbins et al and Aspinal et al teaches that malted grain are known to be rich in amino acids and sugars. See the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the method of Johnstone for regulating the flux of fluid and electrolyte in the intestine of an animal so that I ml blood of said animal will contain at least 0.5 unit of ASP because Johnstone's method is known to preventing diarrhea and is known to containing the active ingredients of Lange, i.e., amino acid and sugar, and food composition containing amino acid and sugar useful for preventing diarrhea is known to increase the concentration of ASP in the said animal blood. Further more, any common grain, including barley, wheat, corn, or rice, would have been expected to be similarly useful in Johnstone's method.

10. Claims 26-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolles et al. (US 4,834,989) and Camburn (US 5,552,175) in view of Witt et al. (US 4,241,183).

Bolles et al. teach a flaked cereal and the method of making the same. The method comprising employing products having enzymatic activity, such as malted wheat, malted barley or malted sorghum. See, the abstract, column 3, lines 47-53, column 24-39. Camburn further teach a powdered foodstuff prepared with malted cereals. See, the examples in columns 6-9.

The primary references do not teach expressly a method for regulating the flux of fluid and intestine of human so that 1 ml of blood will contain at least 0.5 units of ASP.

However, people who consume the food containing malted grain would have reasonably expected to have ASP level more than 0.5unit/ml, absent evidence to the contrary. Witt et al. further teach that it is well known that malted cereal contain enzyme and are widely used in food products. See, column 1, lines 5-10.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to let people consume the food product of malted cereal in the product of Bolles et al and Camburn (US 5,552,175) or food product contain some of malted cereal as suggested by Witt. The instant claims are directed to effecting a biochemical pathway with an old and well known composition. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Additionally, where the patent Office has reason to believe that a functionally limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it

possesses the authority to requires the applicant to prove that the subject matter shown to be in the prior art does not posses the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, (i.e., consuming food product containing malted cereal), albeit distanced by various biochemical intermediates. The ultimate utility for the claimed composition is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

S. Wang

Shengjun Wang

AU 1617

August 23, 2001

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200